UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC, Plaintiffs, v. ACTAVIS SOUTH ATLANTIC LLC, AUROBINDO PHARMA LTD., AUROBINDO PHARMA USA INC., MYLAN PHARMACEUTICALS INC., PAR PHARMACEUTICAL, INC., RANBAXY INC., RANBAXY LABORATORIES LIMITED, SUN PHARMACEUTICAL INDUSTRIES, INC., SUN PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., TORRENT PHARMA INC. and TORRENT PHARMACEUTICALS LIMITED Defendants.	)	C.A. No. 1:07-cv-00572-GMS

FIRST AMENDED ANSWER
AND COUNTERCLAIMS OF DEFENDANT
PAR PHARMACEUTICAL, INC. TO PLAINTIFFS' COMPLAINT

Defendant Par Pharmaceutical, Inc. ("Par") hereby responds to the corresponding paragraphs of the Complaint of the plaintiffs, sanofi-aventis and sanofi-aventis U.S. LLC ("sanofi-aventis U.S.") as follows:

1. Par has insufficient knowledge to admit or deny the allegations in Paragraph 1 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

2. Par has insufficient knowledge to admit or deny the allegations in Paragraph 2 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

3. Upon information and belief, Par admits the allegations in Paragraph 3 of the Complaint.

4. Par has insufficient knowledge to admit or deny the allegations in Paragraph 4 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

5. Par has insufficient knowledge to admit or deny the allegations in Paragraph 5 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

6. Par has insufficient knowledge to admit or deny the allegations in Paragraph 6 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

7. Par admits the allegations in Paragraph 7 of the Complaint.

8. Par has insufficient knowledge to admit or deny the allegations in Paragraph 8 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

9. Par has insufficient knowledge to admit or deny the allegations in Paragraph 9 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

10. Par has insufficient knowledge to admit or deny the allegations in Paragraph 10 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

11. Par has insufficient knowledge to admit or deny the allegations in Paragraph 11 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

12. Par has insufficient knowledge to admit or deny the allegations in Paragraph 12 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

13. Par has insufficient knowledge to admit or deny the allegations in Paragraph 13 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

14. Par has insufficient knowledge to admit or deny the allegations in Paragraph 14 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

15. The allegations of Paragraph 15 of the Complaint set forth legal conclusions and characterizations. The Complaint speaks for itself, and no further response by Par is required, except to state that the Complaint purports to state a cause of action under Title 35 of the U.S. Code.

16. Par admits the allegations in Paragraph 16 of the Complaint.

17. Par denies the allegations in Paragraph 17 of the Complaint, except to state that it does not contest personal jurisdiction over itself in this proceeding.

18. Upon information and belief, Par admits the allegations in

Paragraph 18 of the Complaint.

19. Par has insufficient knowledge to admit or deny the allegations in Paragraph 19 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

20. Par has insufficient knowledge to admit or deny the allegations in Paragraph 20 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

21. Par has insufficient knowledge to admit or deny the allegations in Paragraph 21 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

22. Par admits the allegations in Paragraph 18 of the Complaint.

23. Par has insufficient knowledge to admit or deny the allegations in Paragraph 23 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

24. Par has insufficient knowledge to admit or deny the allegations in Paragraph 24 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

25. Par has insufficient knowledge to admit or deny the allegations in Paragraph 25 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

26. Par has insufficient knowledge to admit or deny the allegations in Paragraph 26 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

27. Par has insufficient knowledge to admit or deny the allegations in Paragraph 27 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

28. Par has insufficient knowledge to admit or deny the allegations in Paragraph 28 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

29. Par has insufficient knowledge to admit or deny the allegations in Paragraph 29 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

30. Par admits the allegations in Paragraph 30 of the Complaint with respect to itself. Par has insufficient knowledge to admit or deny the allegations in Paragraph 30 of the Complaint with respect to any other defendant, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

31. Par admits that the '491 patent was issued by the United States Patent and Trademark Office ("PTO") on April 28, 1987, that sanofi-aventis U.S. holds NDA No. 21-287 on Uroxtral® brand alfuzosin hydrochloride extended release tablets, and that the '491 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") with respect to Uroxtral®. Par denies that the '491 patent was duly and legally issued by the PTO. Par has insufficient knowledge to admit or deny the remaining allegations, and therefore denies the same.

32. Par admits that the '940 patent was issued by the PTO on November 21, 2000, and that the '940 patent is listed in the Orange Book with respect to Uroxtral®. Par denies that the '940 patent was duly and legally issued by the PTO. Par has

insufficient knowledge to admit or deny the remaining allegations, and therefore denies the same.

33. Upon information and belief, Par admits the allegations in Paragraph 33 of the Complaint.

34. The statements made in Actavis' ANDA No. 79-055 speak for themselves and require no further response by Par. Par has insufficient knowledge to admit or deny the remaining allegations in Paragraph 34 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

35. Upon information and belief, Par denies the allegations in Paragraph 35 of the Complaint.

36. Par denies the allegations in Paragraph 36 of the Complaint.

37. Par denies the allegations in Paragraph 37 of the Complaint.

38. Par denies the allegations in Paragraph 38 of the Complaint.

39. Par denies the allegations in Paragraph 39 of the Complaint.

40. Upon information and belief, Par admits the allegations in Paragraph 40 of the Complaint.

41. The statements made in Actavis' ANDA No. 79-055 speak for themselves and require no further response by Par. Par has insufficient knowledge to admit or deny the remaining allegations in Paragraph 41 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

42. Upon information and belief, Par denies the allegations in Paragraph 42 of the Complaint.

43. Par denies the allegations in Paragraph 43 of the Complaint.

44. Par denies the allegations in Paragraph 44 of the Complaint.

45. Par denies the allegations in Paragraph 45 of the Complaint.

46. Par denies the allegations in Paragraph 46 of the Complaint.

47. – 108. Par has insufficient knowledge to respond to the allegations in Paragraphs 47 – 108 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

FIRST AFFIRMATIVE DEFENSE

Invalidity

1. The '491 patent is invalid and unenforceable by reason of the failure of the '491 patent to satisfy one or more conditions of patentability specified in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103 and 112.

2. The '940 patent is invalid and unenforceable by reason of the failure of the '940 patent to satisfy one or more conditions of patentability specified in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103 and 112.

COUNTERCLAIMS

The Parties

1. Par Pharmaceutical, Inc. ("Par") is a corporation established under the laws of Delaware, having a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

2. Upon information and belief, sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

3. Upon information and belief, sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware, with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

Declaration of Noninfringement and Invalidity

4. Par repeats and realleges Paragraphs 1-3 of the counterclaims.

5. This claim arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

6. In their Complaint, sanofi-aventis and sanofi-aventis U.S. assert that Actavis infringed United States Patent No. 4,661,491 ("the '491 patent") and United States Patent No. 6,149,940 ("the '940 patent") by submitting Abbreviated New Drug Application ("ANDA") No. 79-055 including the § 505(j)(2)(A)(vii)(IV) allegations to the Food and Drug Administration ("FDA"), and that through ANDA No. 79-055 Actavis seeks FDA approval to manufacture and sell alfuzosin hydrochloride extended release tablets prior to the expiration of the '491 and '940 patents.

7. Par seeks a declaration that the '491 and '940 patents are not infringed and that the '491 and '940 patents are invalid.

8. The '491 patent was issued by the PTO on April 28, 1987, and currently names sanofi-aventis as the assignee of the named inventor Francois Regnier.

9. In their Complaint, sanofi-aventis and sanofi-aventis U.S. maintain, and Par denies, that Par's participation in, contribution to, aiding, abetting and/or inducing Actavis' submission of ANDA No. 79-055 infringes the '491 patent under 35 U.S.C. § 271(e)(2)(A) and that Par's commercial use, offer for sale or sale of its alfuzosin

hydrochloride extended release tablets would infringe the ‘491 patent. In their Complaint, sanofi-aventis and sanofi-aventis U.S. maintain, and Par denies, that the ‘491 patent is valid.

10. Par’s participation in, contribution to, aiding, abetting and/or inducing Actavis’ submission of ANDA No. 79-055 does not infringe the ‘491 patent under 35 U.S.C. § 271(e)(2)(A), and Par’s commercial use, offer for sale or sale of its alfuzosin hydrochloride extended release tablets would not infringe the ‘491 patent.

11. The ‘491 patent is invalid by reason of its failure to satisfy one or more conditions of patentability specified in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103 and 112.

12. The ‘940 patent was issued by the PTO on November 21, 2000, and currently names sanofi-aventis and Jagotec AG as the assignees of the named inventors Lauretta Maggi, Ubaldo Conte, Pascal Grenier, Guy Vergnault, Alain Dufour, Francois Xavier Jarreau, and Clemence Rauch-Desanti.

13. In their Complaint, sanofi-aventis and sanofi-aventis U.S. maintain, and Par denies, that Par’s participation in, contribution to, aiding, abetting and/or inducing Actavis’ submission of ANDA No. 79-055 infringes the ‘940 patent under 35 U.S.C. § 271(e)(2)(A) and that Par’s commercial use, offer for sale or sale of its alfuzosin hydrochloride extended release tablets would infringe the ‘940 patent. In their Complaint, sanofi-aventis and sanofi-aventis U.S. maintain, and Par denies, that the ‘940 patent is valid.

14. Par’s participation in, contribution to, aiding, abetting and/or inducing Actavis’ submission of ANDA No. 79-055 does not infringe the ‘940 patent under 35

U.S.C. § 271(e)(2)(A), and Par's commercial use, offer for sale or sale of its alfuzosin hydrochloride extended release tablets would not infringe the '940 patent.

15. The '940 patent is invalid by reason of its failure to satisfy one or more conditions of patentability specified in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103 and 112.

16. Actual and justiciable controversies exist between Par and sanofi-aventis/sanofi-aventis U.S. regarding the infringement and validity of the '491 and '940 patents.

17. Par is entitled to declarations that Par's participation in, contribution to, aiding, abetting and/or inducing Actavis' submission of ANDA No. 79-055 does not infringe the '491 and '940 patents under 35 U.S.C. § 271(e)(2)(A) and that Par's commercial use, offer for sale or sale of its alfuzosin hydrochloride extended release tablets would not infringe the '491 and '940 patents.

18. Par is entitled to declarations that the '491 and '940 patents are invalid.

PRAYER FOR RELIEF

WHEREFORE, Par demands judgment in its favor and against sanofi-aventis, and respectfully request that this Court:

(a) Dismiss the Complaint with prejudice and deny each request for relief made by sanofi-aventis and sanofi-aventis U.S.;

(b) Adjudge the claims of the '491 patent not infringed;

(c) Adjudge the claims of the '940 patent not infringed;

(d) Adjudge the claims of the '491 patent invalid;

(e) Adjudge the claims of the '940 patent invalid;

(f) Declare this case to be exceptional under 35 U.S.C. § 285;

(g) Award Par its attorneys' fees pursuant to 35 U.S.C. § 285, other statutes or rules, or general power of the Court;

(h) Preliminarily and permanently enjoin sanofi-aventis and sanofi-aventis U.S., their officers, agents, servants, employees, attorneys and any person who acts in concert or participation with sanofi-aventis and/or sanofi-aventis U.S ., from utilizing the '491 patent to block, hamper, hinder or obstruct FDA approval of the product described in ANDA No. 79-055;

(i) Preliminarily and permanently enjoin sanofi-aventis and sanofi-aventis U.S., their officers, agents, servants, employees, attorneys and any person who acts in concert or participation with sanofi-aventis and/or sanofi-aventis U.S., from utilizing the '940 patent to block, hamper, hinder or obstruct FDA approval of the product described in ANDA No. 79-055;

(j) Permanently enjoin sanofi-aventis and sanofi-aventis U.S., its officers, agents, servants, employees, attorneys and any person who acts in concert or participation with sanofi-aventis and/or sanofi-aventis U.S., from asserting or otherwise seeking to enforce the '491 patent against Par or anyone in privity with Par;

(k) Permanently enjoin sanofi-aventis and sanofi-aventis U.S., its officers, agents, servants, employees, attorneys and any person who acts in concert or participation with sanofi-aventis and/or sanofi-aventis U.S., from asserting or otherwise seeking to enforce the '940 patent against Par or anyone in privity with Par; and

(l) Award Par such other and further relief as the Court deems just and proper.

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Dated: November 16, 2007

CERTIFICATE OF SERVICE

I, Dominick T. Gattuso, hereby certify that on November 16, 2007, I caused to be electronically filed a true and correct copy of the First Amended Answer and Counterclaims with the Clerk of the Court using CM/ECF that will send notification of such filing to the following counsel of record:

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I further certify that on November 16, 2007, I caused copies of the foregoing document to be served by e-mail on the following.

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